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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/819,193	03/28/2001	Charleata A. Carter	8263.03	2906

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JOE D. CALHOUN  
319 PRESIDENT CLINTON AVENUE  
SUITE 205  
LITTLE ROCK, AR 72201

EXAMINER
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CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/819,193

Applicant(s)

CARTER

Examiner

Karen A Canella

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_ .
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 21--39 is/are pending in the application.
- 4a) Of the above claim(s) 31-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 21-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_ .
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_ .

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### DETAILED ACTION

1. Claims 1-13 have been canceled. claims 21-39 have been added. Claims 31-39, drawn to non-elected inventions, are withdrawn from consideration. Claims 21-30 are under consideration.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 21 and 26 recite the limitation "having characteristic consistent with primary tumor". claim 26 additionally recites "response to an anti-cancer compound in substantially equivalent ways...as said specimen". The metes and bounds of "characteristics consistent with" the primary tumor and "substantially equivalent ways as said specimen" cannot be determined. Primary tumors have multiple characteristics and it is unclear what a characteristic "consistent with" said primary tumor encompasses. Further it is unclear what "substantially equivalent" encompasses in reference to said specimen.

Claim 25 is vague and indefinite in the recitation of a karyotype including "?". because the "?" indicates questionable identification of chromosome or chromosome structure. Thus the metes and bounds of the cell lines encompassed by the recited karyotype is unknown.

Claim 30 is vague and indefinite in the recitation of "superficially" invasive. The specification is lacking a definition for "superficially invasive" that would distinguish it from "invasive".

4. The rejection of claim 25 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for lacking a deposit of biological material is maintained for reasons

of record. Applicants intention of making the required deposit after indication of allowability is noted.

5. Claim 30 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The addition of new claim 30 containing the specific embodiment "superficially invasive" is not supported by the specification as originally filed. Applicant is invited to point out by page and line number textual support for claim 30.

6. Claims 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Carter et al (Anticancer Research, 1997, Vol. 17, pp. 1973-1984, cited in a previous Office action) as evidenced from the abstract of Siddiqui et al (British Journal of Cancer, 1994, Vol. 69, suppl. 21, page 18.).

Claim 26 is drawn to a line of cells originating from a specimen of poorly differentiated human endometrial adenocarcinoma that is metastatic, said cells having characteristics consistent with primary tumor, wherein a plurality of said cells response to an anti-cancer compound in substantially equivalent ways at the cellular level as said specimen. claim 27 embodies the cell line of claim 26 wherein said anti-cancer agent comprises a differentiating agent. claim 28 embodies the cell line of claim 27 wherein said differentiating agent comprises retinoic acid. Claim 29 embodies the cellular composition of claim 26 wherein said cells are grown in-vitro as a monolayer. Claim 30 embodies the cellular composition of claim 26 wherein said original specimen is superficially invasive. It is noted that the metes and bounds of claim 30 cannot be determined for the reasons set forth in the rejection under 112, second paragraph, above.

Carter et al disclose a cellular composition comprising KLE cells which are poorly differentiated endometrial adenocarcinoma cells that grown in a monolayer. Siddiqui et al disclose that KLE cells are from a grade 3 human endometrial adenocarcinoma, thus fulfilling the specific embodiment of originating from a poorly differentiated human endometrial adenocarcinoma that is metastatic. Carter et al disclose that the KLE cells exhibit reorganization

of F-actin when treated with retinoic acid (page 1977, bridging paragraph, columns 1-2), thus fulfilling the specific embodiments of claims 27 and 28). Claim 30 is included in this rejection, as it is unclear what constitutes a "superficially invasive" specimen and further that the KLE cell line appears to have the same characteristics as claimed. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

7. Claims 21-24 and 26-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Gal et al (*Gynecologic Oncology*, 1982, Vol. 13, pp. 50-57, cited in a previous Office action).

Claim 21 is drawn to a hyperdiploid cellular composition comprising cells isolated for a poorly differentiated human endometrial adenocarcinoma that is metastatic, said cells having the characteristic consistent with the primary tumor. Claim 22 embodied the method of claim 21 wherein the plurality of cells have at least 48 chromosomes. Claim 23 embodies the cellular composition of claim 22 wherein a plurality of cells are at least triploid at chromosome 3. Claim 24 embodies the cellular composition of claim 22 wherein a plurality of cells are at least triploid at chromosome 17.

Gal et al disclose the tumor cell line AC-258, growing as a monolayer and originating from a patient with a poorly differentiated adenocarcinoma of the endometrium (page 1864, second column, lines 2-4 and lines 9-10 under the heading "Materials and Methods". Gal et al disclose that the tumor from which the cell line was derived was a stage Ib, Grade 3 tumor, hence the tumor was metastatic. Gal et al disclose that the average number of chromosomes per cell was 64.8, thus fulfilling the specific embodiment of claim 22 wherein a plurality of cells has at least 48 chromosomes. Gal et al further disclose that histological evaluation of tumor explants revealed the same morphological identity as the tumor (Figures 1B-D). Gal et al do not specifically disclose that the cells were triploid at chromosomes 3 and 17, however, Gal et al


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disclose that trisomy was common (page 55, lines 5-6). Gal et al do not specifically disclose that the AC-258 cell line would comprise a plurality of cells which would respond to an anti-cancer compound in substantially equivalent ways as said specimen, however, Gal et al state that "The growth of the tumor in vitro appeared to mimic its in vivo virulence" (page 56, lines 1-2), therefore, it would be inherent in the specimen that a plurality of cells would respond to an anti-cancer compound in substantially equivalent ways. The Office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

8. All other rejections and objections as set forth in Paper No. 6 are withdrawn in light of applicants Declaration.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

  
Karen A. Canella, Ph.D.  
Patent Examiner, Group 1642  
9/8/03